August 28, 2020

Advanced Orthopaedic Solutions, Inc.
Jolie Krance
Senior Regulatory Affairs Specialist
3203 Kashiwa Street
Torrance, California 90505

Re: K202099
Trade/Device Name: AOS Galileo™ Trochanteric Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: July 29, 2020
Received: July 30, 2020

Dear Jolie Krance:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael Owens
Assistant Director
DHT6A: Division of Joint
Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

ADVANCED ORTHOPAEDIC SOLUTIONS

Special 510(k) Summary

Date Prepared	August 21, 2020
Submitted by	Advanced Orthopaedic Solutions, Inc 3203 Kashiwa Street Torrance, CA 90505 Phone: (310) 533-9966
Establishment Registration	2032480
Owner Operator Number	9046896
Regulatory Contact	Jolie Krance Senior Regulatory Affairs Specialist Advanced Orthopaedic Solutions, Inc. 3203 Kashiwa Street Torrance, CA 90505 (310) 533-9966 jkrance@aosortho.com
Device Name	AOS Galileo™ Trochanteric Nail System
Common Name	Trochanteric Intermedullary Nail System
Classification	Class II, 21 CFR 888.3020 Intramedullary Fixation Rod
Device Code	HSB — Rod, Fixation, Intramedullary and Accessories

ADVANCED ORTHOPAEDIC SOLUTIONS

AOS Legally Marketed Substantially Equivalent Devices	Primary — AOS Galileo™ Trochanteric Nail System – Lag Screw (K120148, Cleared October 2, 2012) Additional — AOS Galileo™ Trochanteric Nail System (K021008, Cleared June 20, 2002), and AOS Galileo™ Trochanteric Nail System - ES Nail (K103533, Cleared January 19, 2011)
Device Description	The AOS Galileo™ Trochanteric Nail System is a single-use, open reduction and internal fixation device, comprised of the Trochanteric Intermedullary Nail, Telescoping Lag Screws, Anti Rotation Screw, Cortical Locking Bone Screws, and their dedicated accessories, and sterilization trays. The trochanteric nail is a side specific cannulated femoral intramedullary nail with a proximal bend that is designed to enter through the greater trochanter, for the treatment of fractures to the femur, including peritrochanteric, intertrochanteric, high subtrochanteric fractures, and combinations thereof. The device is meant to be used as a load sharing device, and it may be removed once the fracture is healed.
Indications for Use	The AOS Galileo™ Trochanteric Nail System is intended to treat stable and unstable proximal fractures of the femur including peritrochanteric, intertrochanteric and high subtrochanteric fractures and combinations of these fractures. The long trochanteric nail is additionally indicated for subtrochanteric fractures, peritrochanteric fractures associated with shaft fractures, pathologic fractures (including prophylactic use) in osteoporotic bone of the trochanteric and diaphyseal areas, long subtrochanteric fracture, ipsilateral femoral fractures, proximal and distal non-unions and malunions and revisions procedures.
Technological Characteristics	The AOS Galileo Trochanteric Nail System subject device has similar technological charateristics to the identified predicates. The material and chemical composition, performance requirements, and method of operation are identical to the predicate devices.

Substantial Equivalence	The subject AOS Galileo™ Trochanteric Nail System, the predicates AOS Galileo™ Lag Screw (K120148) AOS Galileo™ Trochanteric Nail System (K021008), and the AOS Galileo™ Trochanteric ES Nail (K103533), have the same intended use, patient population, operating principle, and risk profile. They have identical manufacturing, packaging, sterilization parameters, and shipping processes, all of which will be conducted under the same quality management system.
Nonclinical Testing	The AOS Galileo™ Trochanteric Nail System was subjected to functional testing and strength comparison analysis. The results demonstrate that the Galileo™ Intramedullary Nails and accessories are substantially equivalent to the predicates.
Conclusion	Since the device has the same intended use and similar technological characteristics to the identified predicates, the device does not raise any different questions of safety or effectiveness. The performance testing and engineering analysis demonstrated that the subject device had substantially equivalence performance. Therefore, the premarket notification demonstrated that the device is substantially equivalent to the predicate